January 11, 2025

Shenzhen Yattll Industry Co., Ltd
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Co. Ltd.
14th Floor, 1500# Century Avenue
Shanghai, Shanghai 200122
China

Re: K241641
Trade/Device Name: Electric Wheelchair (YE200)
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: December 12, 2024
Received: December 12, 2024

Dear Ivy Wang:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241641

Device Name

Electric Wheelchair (YE200)

Indications for Use *(Describe)*

The Electric wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K241641

I. SUBMITTER

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Date prepared: 2024-12-12

II. Device

Device trade name: Electric Wheelchair

Model: YE200

Classification name: Powered wheelchair

Regulation class: 2

Regulation number: 21CFR 890.3860

Panel: Physical Medicine

Product code: ITI

III. Predicate device

K212092

Electric Wheelchair, DC01

Anhui JBH Medical Apparatus Co., Ltd.

IV. Device description

The Electric wheelchair, YE200, is a powered wheelchair that is designed to fold when not in use so it can be more easily transported in a car trunk or similar space. It uses rechargeable lithium batteries, and is controlled by a joystick and a few other simple controls which are located on the end of the armrest. The joystick assembly may be installed on either side of the chair to accommodate both right-handed and left-handed users.

The Electric wheelchair consists of two armrests, a back rest, a seat cushion, a foldable frame, two rear drive wheels with hub motor and electromagnetic brake assemblies, two pivoting casters, two Li-ion battery pack, an off-board battery charger, a control panel (joystick) with connect cables and an electric motor controller. The device is powered by Li-ion battery pack, which can be recharged by an off-board battery charger that can be plugged into an AC socket outlet when the device is not in use.

The user can activate the controller handle (joystick) to control the speed and direction of the wheelchair movement. In addition, when the patient releases the joystick, the joystick will return back to the central position and the wheelchair will be automatically stopped soon due to automatic electromagnetic brake system. Once the joystick is activated again move to other position, the wheelchair will be re-energized.

V. Indication for use

The Electric wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position. It is suitable for disabled people with mobility difficulties and elderly people.

VI. Comparison of technological characteristics with the predicate device

Attribute	Predicate device	Subject device	Discussion/ Conclusion
Proprietary name	Electric wheelchair	Electric wheelchair	/
Model	DC01	YE200	/
510(k) number	K212092	K241641	/
Device classification name	Class II	Class II	Same
Classification regulations	21 CFR 890.3860	21 CFR 890.3860	Same
Product code	ITI	ITI	Same
Similarities			
Indication for use	The wheelchair (Model: DC01) is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	The Electric wheelchair is a motor driven, indoor and outdoor transportation vehicle with the intended use to provide mobility to a disabled or elderly person limited to a seated position.	Same

Attribute	Predicate device	Subject device	Discussion/ Conclusion
Intended user	disabled people and elderly people	disabled people and elderly people	Same
Use condition	indoor and outdoor use	indoor and outdoor use	Same
Number of wheels	4, including two front wheels and two rear wheels	4, including two pivoting casters and two rear drive wheels	Same
Function of wheels	Front wheels: driven wheels suitable for rotation, acceleration, retrograde Rear wheels: driving wheels to control the speed and direction	two front casters: driven wheels suitable for rotation, acceleration, retrograde two rear wheels: driving wheels to control the speed and direction	Same
Folding mechanism	front and rear folding	front and rear folding	Same.
Movement control method	By Joystick control	By Joystick control	Same
Driving system	Direct drive on the rear wheels	Direct drive on the rear wheels	Same
Brake system	Smart Electromagnetic brake	Automatic electromagnetic brake	Same
Electronic controller	Dual Drive Controller for Brushless	Dual Drive Controller for Brushless	Same
Motor	Brushless DC motor 180W x 24 VDC x 2 pcs	Brushless DC motor; 24 VDC; 180 W; 2 pcs	Same
Max loading weight	120 kg (264 lbs)	120 kg (264 lbs)	Same
Armrest	PU (polyurethane)	PU (polyurethane)	Same
Differences			
Frame design and material	The frame of the wheelchair is type capable of front and rear close. The main part of the frame can be folded for saving space and convenient storage and transportation. The main frame is made of carbon fiber material.	The frame of the wheelchair is type of aluminum frame with front and rear folding structure and flip-up armrest. The main frame is made of Aluminum alloy material.	Although the different frame material used on the subject device compared to the predicate device, while all safety and performance tests are conducted on the subject device and all passed. Such difference will not affect the safety and performance of the subject device.

Attribute	Predicate device	Subject device	Discussion/ Conclusion
Overall dimensions (LxWxH)	1110 mm x 700 mm x 980 mm	1107mmX620mmX950mm	Minor difference on wheelchair dimensions will not cause different performance. All safety and performance have been validated with the maximum rated weight dummy.
Folded dimensions (LxWxH)	810 mm x 700 mm x 400 mm	420mmX620mmX800mm	
Ground clearance	160 mm	100mm	Minor difference on ground clearance will not impact the safety and effectiveness of the subject device.
Front wheel size/type	182mm*45mm (7" x 1.75") /PU Solid tire	182mm*55mm (7" x 2.1")/ PU Solid tire	Minor difference on dimension of wheels will not cause different performance.
Rear wheel size/type	203mm*50mm (8"x1.95") /PU solid tires	350mm*61mm (13.7" x 2.4")/ PU solid tire	
Max speed forward	6 km/h	5.7km/h	Minor difference on max. forwarding speed will not cause different performance.
Minimum braking distance from maximum speed	Forward: 0.5m	Forward: 0.75 m	Minor difference on braking distance between subject device and predicate device, while all relevant tests are performed according to ISO 7176-3, no safety and effectiveness concerns will be affected.
Maximum safe operational incline degree	8 °	6 °	Minor difference on safe operational incline degree will not cause new safety and effectiveness concerns are raised as both the static and dynamic stability under specific inclining degree have been evaluated according to standard ISO 7176 series.
Battery charger	Off-board charger Input: 100-240V, 50/60Hz, 1.5A, Output: 24 Vdc, 2A;	Off-board charger Input: 100-240V, 50/60Hz, 1.1A, Output: 24 Vdc, 2A;	Minor input current difference will not cause new safety and effectiveness concerns raised.
Battery	Lithium-ion, 24V6Ah, 6Ah x 24 VDC	Li-ion battery, Rechargeable; 24 VDC 7.8Ah*2	Same rated voltage, minor difference on battery capacity will not cause different performance. This difference will not raise any new safety and effectiveness concerns.

Attribute	Predicate device	Subject device	Discussion/ Conclusion
Maximum distance of travel on the fully charged battery	20 km	16 km	Minor difference on travel distance will not cause different performance. This difference will not raise any new safety and effectiveness concerns.
Turning Radius	800 mm	875 mm	The minor difference in the turning radius is caused by different size of wheelchair and may cause a little bit inconvenience when it turns in a narrow space while the minor difference will not raise any new safety and effectiveness concerns.
Maximum obstacle climbing	20 mm	15 mm	Minor difference in the obstacle climbing will not impact the safety and effectiveness of the subject device.
back and sea cushion	linen cloth filled with PU foam	Polyester Mesh fabric filled with sponge	Different material used for parts in contact with user, which such differences will not impact the safety and effectiveness of the subject device as biocompatibility tests are carried out according to ISO 10993 series.

VII. Summary of substantial equivalence discussion

The subject electric wheelchair complied with the requirements of ISO 7176-1:2014, ISO 7176-2:2017, ISO 7176-3:2012, ISO 7176-4:2008, ISO 7176-5:2008, ISO 7176-6:2018, ISO 7176-7:1998, ISO 7176-8:2014, ISO 7176-9:2009, ISO 7176-10:2008, ISO 7176-11:2008, ISO 7176-13:1989, ISO 7176-14:2008, ISO 7176-15:1996, ISO 16840-10: 2021, ISO 7176-21:2009, ISO 7176-22:2014, ISO10993-5:2009, ISO 10993-10:2021, ISO 10993-23: 2021, IEC 60601-1-2: 2020.

The intended uses for both devices are the same. Both mainframes of the two devices are folded by way of front and rear close. As for different frame materials used and minor difference on safe operational incline degree for both devices, considering all safety and performance tests are carried out on the subject device with favorable result, such difference will not affect the safety and performance of the subject device. The design principles of the

controller and Driving system are the same, and both meet the requirements of the ISO 7176-14:2008. Software validation is carried out on both control systems. Brake system and speed control are designed in the same way as well, and both meet the requirements of the ISO 7176-3:2012. Turning radius, Maximum obstacle climbing and ground clearance are slightly different while such differences will not impact the safety and effectiveness of the subject device or raise new safety and effectiveness concerns as well as both meet the requirements of the ISO 7176-2:2017, ISO 7176-10:2008.

The biocompatibility of the Predicate device and Subject device meet the requirements of the ISO 10993-5:2009 & ISO 10993-10:2021 & ISO 10993-23: 2021.

All seat cushion/back cushion and armrest are made of flame retardant material for both devices. Therefore, both devices are assured to be under the same safety level.

In conclusion, the technological characteristics, features, specifications, materials, mode of operation, and intended use of the device substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

VIII. Summary of non-clinical testing

➢ Performance testing-bench

The following performance data were provided to verify that the subject device met all design specifications and provided support of the substantial equivalence determination.

- Risk Analysis developed in accordance with ISO 14971: 2019.
- Software validation
- ISO 7176-1:2014 Wheelchairs - Part 1: Determination of static stability
- ISO 7176-2:2017 Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs
- ISO 7176-3:2012 Wheelchairs - Part 3: Determination of effectiveness of brakes
- ISO 7176-4:2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
- ISO 7176-5:2008 Wheelchairs - Part 5: Determination of dimensions, mass and maneuvering space

- ISO 7176-6:2018 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
- ISO 7176-7:1998 Wheelchairs - Part 7: Measurement of seating and wheel dimensions
- ISO 7176-8:2014 Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strength
- ISO 7176-9:2009 Wheelchairs - Part 9: Climatic tests for electric wheelchairs
- ISO 7176-10:2008 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
- ISO 7176-11:2012 Wheelchairs -- Part 11: Test dummies
- ISO 7176-13:1989 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces.
- ISO 7176-14:2022 Wheelchairs -- Part 14: Power and control systems for electrically powered wheelchairs and scooters -- Requirements and test methods
- ISO 7176-15:1996 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling.
- ISO 16840-10:2021 Wheelchair seating - Part 10: Resistance to ignition of postural support devices - Requirements and test method.
- ISO 7176-21:2009 Wheelchairs - Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters
- ISO 7176-22: 2014 Wheelchairs - Part 22: Set-up procedures
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2020.

➢ Biocompatibility of patient-contacting material

Biocompatibility Tests are carried out in accordance with ISO10993-1: 2018, including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2021) and irritation (ISO 10993-23: 2021). Details of the test summary see biocompatibility summary.

IX. Summary of clinical testing

No animal study and clinical studies are available for our device. Clinical testing was not required to demonstrate the substantial equivalence of the power wheelchair to its predicate

device.

X. Conclusions

The conclusion drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K212092.